UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	MDL No. 02419 Docket No. 1:13-md-2419-RWZ
This document relates to:	)	
Handy v. Box Hill Surgery Center, LLC, et al. No: 1:14-cv-14019-RWZ	)	
Armetta v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14022-RWZ	)	
Torbeck v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14023-RWZ	)	
Kashi v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14026-RWZ	)	
Bowman v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14028-RWZ	)	
Dreisch v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14029-RWZ	)	
Davis v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14033-RWZ	)	
Farthing v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14036-RWZ	)	

BOX HILL DEFENDANTS' CONSOLIDATED MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR PARTIAL SUMMARY JUDGMENT CONCERNING PLAINTIFFS' CLAIMS RELATING TO PATIENT-SPECIFIC PRESCRIPTIONS

Defendants, Box Hill Surgery Center, L.L.C., Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., L.L.C. (hereinafter, collectively "Defendants," "Box Hill Defendants," or "Box Hill"), by undersigned counsel, submit this memorandum of law in support of their Motion For

Summary Judgment, pursuant to Rule 56 of the Federal Rules of Civil Procedure and the authority cited below.

I. INTRODUCTION

In each of the above captioned cases, Plaintiffs asserted claims alleging that the Box Hill Defendant alleged negligence in failing to order medications from NECC using patient-specific prescriptions caused Plaintiffs' injuries. The Box Hill Defendants now move for summary judgment on such claims because Plaintiffs are unable to establish the causation element of their negligence claim.

The Court is well-versed on the background of these cases. Accordingly, the Defendants will refrain from restating all of the issues in these cases, which otherwise do not apply to the singular claim addressed in this motion for summary judgment.

This action is among hundreds, if not thousands, of lawsuits across the United States arising out of the administration of a steroid—preservative free methylprednisolone acetate (hereinafter "MPA")—manufactured, contaminated, and distributed by New England Compounding Pharmacy, Inc. a/k/a New England Compounding Center (hereinafter "NECC"), a now dissolved corporation in Massachusetts. NECC provided MPA for purchase nationally to many physicians, ambulatory surgery centers, clinics, and hospitals, including Defendant Box Hill Surgery Center, which is an ambulatory surgery center solely owned by Defendant Bhambhani. It is alleged that as a result of negligent manufacturing, cleaning and sterilization practices by NECC, as well as improper testing and "clean-room" design, that certain vials or batches of MPA became contaminated with fungus in 2012 and may have caused varying levels of harm or injury to patients, who had received the MPA from their health care providers. It is alleged that the

contaminated vials were limited to certain lots: Lot # 05212012@68 (BUD 11/17/2012); Lot # 06292012@26 (BUD 12/26/2012); and Lot # 08102012@51 (BUD 2/6/2013).

The MPA in these lots was shipped to health care providers, including the Box Hill Defendants, who administered the drugs to patients before it was discovered that the lots were contaminated. These lots were recalled by NECC under pressure from the CDC on or about September 26, 2012, but not until after numerous patients fell ill, and some died, after developing fungal meningitis or other neurologic or infectious process.

It is alleged that the Box Hill Defendants were negligent in failing to provide patient-specific prescriptions in order to purchase medication from NECC. Assuming arguendo that such allegations are true, which they are not, such allegations are also insufficient to plead causation, either factual or proximate. NECC's failure to properly manufacture and apply proper sterility and testing practices as to MPA was the source of the contamination, not an alleged failure to provide patient-specific prescriptions. In other words, even assuming that the Box Hill Defendants had provided patient-specific prescriptions to the satisfaction of the Plaintiffs in this case, that would not have caused otherwise contaminated medication to transform into an unadulterated form to be administered to the Plaintiff patients. Plaintiffs do not plead otherwise. The Box Hill Defendants still would have received contaminated medication from the same supply, the patients still would have been injected with that medication, and the same outcome would have resulted.

As more fully set forth below, the Box Hill Defendants are entitled to summary judgment as to Plaintiffs' claims relating to patient-specific prescriptions because the alleged negligence did not cause Plaintiffs' injuries.

II. STATEMENT OF FACTS[1]

[1] The actual exhibits referenced herein are all included with and following the Statement of Undisputed Material Facts.

1. The Plaintiffs' alleged injuries and causes of action arise from the fungal meningitis outbreak caused by contaminated, preservative-free, methylprednisolone acetate ("MPA") manufactured and sold by the New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC").[2]

2. The tainted vials were limited to certain lots: Lot # 05212012@68 (BUD 11/17/2012); Lot # 06292012@26 (BUD 12/26/2012); and Lot # 08102912@51 (BUD 2/6/2013).[3]

3. The Plaintiffs' claims against the Box Hill Defendants arise from alleged injuries suffered from potential exposure to MPA administered by Dr. Bhambhani and the Box Hill Defendants while performing epidural steroid injection procedures.[4]

4. Dr. Bhambhani and the Box Hill Defendants purchased preservative-free MPA from NECC because her previous employer used it, she had good results with it, and she was concerned about adverse events caused by preservatives.[5]

5. Similarly, thousands of health care providers across the country purchased drugs from the New England Compounding Center ("NECC") even in just the five months preceding the meningitis outbreak at issue.[6]

6. NECC was regulated and inspected by the U.S. Food and Drug Administration ("FDA").[7] In a letter to Mr. Cadden and NECC dated December 4, 2006, the FDA affirmed its position that "the Federal Food, Drug, and Cosmetic Act ("FDCA") establishe[d] agency jurisdiction over 'new drugs,' including compounded drugs."[8]

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[2] Dreisch Complaint at 3, ¶ 1.
[3] Dreisch Complaint at 17, ¶ 51.
[4] Dreisch Complaint at 37, ¶ 145.
[5] *See* Deposition Transcript of Ritu T. Bhambhani, M.D., 71:25–73:16, excerpts attached as **Exhibit 1**.
[6] *See* NECC Customer List Since 5/21/2012, attached as **Exhibit 2**.
[7] *See* FDA Warning Letter, attached as **Exhibit 3**.
[8] *Id*.

7. In addition to such regulatory oversight, NECC also passed the inspection of the Massachusetts Board of Registration in Pharmacy about a year prior to the outbreak, and Brigham and Women's Hospital, a highly accredited and respected healthcare institution, as recently as a week prior to the time that the first batch of recalled MPA solution was manufactured in May 2012.[9]

8. After receiving orders from healthcare providers like Dr. Bhambhani, NECC failed to "follow either the proper USP 797 autoclaving sterilization procedure or its own standard operating procedure," failed to take action on at least twenty-six occasions between January 2012 and September 2012 despite results from an internal environmental monitoring program that recorded bacteria and mold in the clean rooms used to produce "sterile" drug products, and distributed two lots of the recalled MPA before receiving results from sterility testing.[10]

9. The parties are in agreement that the applicable standard of care and professional practice did not require the Box Hill Defendants to travel to the NECC facility to perform an inspection prior to purchasing medications from NECC.[11]

10. On March 22, 2017, Barry Cadden, the owner and head pharmacist of NECC, was convicted by a federal jury of racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead in connection

[9] *See* Commonwealth of Massachusetts Inspection Report, attached as **Exhibit 4**; Brigham and Women's Hospital Department of Pharmacy USP <797> Audit of NECC, attached as **Exhibit 5**; Brigham and Women's Vendor Audit Survey Form, attached as **Exhibit 6**.

[10] Dreisch Complaint at 20, ¶ 66; *Id*. at 22, ¶ 81; *Id*. at 19, ¶ 64.

[11] *See* Deposition Transcript of Dr. Lloyd R. Saberski, 67:7–67:10, excerpts attached as **Exhibit 7**; *see also* Deposition Transcript of Dr. Laxmaiah Manchikanti, 104:10–105:6, excerpts attached as **Exhibit 8**.

with the 2012 nationwide fungal meningitis outbreak.[12] As a result of his criminal conduct, Mr. Cadden was subsequently sentenced to nine years in prison.[13]

11. In the summer and fall of 2012, NECC failed to fulfill its duty to accurately represent the safety and quality of its products to consumer and potential consumers and, in doing so, broke the law.[14]

12. NECC's actions fell below the standard of care with regard to the contaminated lots of MPA.[15]

13. The Box Hill Defendants' procurement of medications from NECC without using patient-specific prescriptions had no effect on whether the medications received were contaminated.[16] Plainly stated, using patient-specific prescriptions would not have prevented Plaintiffs' injuries.[17]

14. The conduct of NECC, rather than the Box Hill Defendants, caused the MPA to be contaminated.[18]

15. NECC's actions were both the actual and proximate cause of the injuries suffered by Plaintiffs.[19]

III. STANDARD OF REVIEW

A moving party is entitled to summary judgment if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no

[12] *Owner of New England Compounding Center Convicted of Racketeering Leading to Nationwide Fungal Meningitis Outbreak*, U.S. DEPT. OF JUSTICE (Mar. 22, 2017), https://www.justice.gov/usao-ma/pr/owner-new-england-compounding-center-convicted-racketeering-leading-nationwide-fungal.
[13] Pharmacist in meningitis outbreak that kills dozens gets 9 years in prison, BOSTON GLOBE (June 26, 2017), https://www.bostonglobe.com/metro/2017/06/26/feds-cadden-should-pay-for-fungal-meningitis-outbreak/kwet31ZTnsT4lpq4WRzkXO/story.html.
[14] *See* Deposition Transcript of Dr. Lloyd R. Saberski, 65:5–65:18, excerpts attached as **Exhibit 7**.
[15] *See* Deposition Transcript of Dr. David Chason, 120:1–121:11, excerpts attached as **Exhibit 9**.
[16] *See* Deposition Transcript of Dr. Lloyd R. Saberski, 167:13–168:16, excerpts attached as **Exhibit 7**.
[17] *See id*.
[18] *See id*., 64:7–65:1, excerpts attached as **Exhibit 7**.
[19] *See* Deposition Transcript of Dr. David Chason, 120:1–121:11, excerpts attached as **Exhibit 9**.

genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(c)(2). The moving party is "entitled to judgment as a matter of law" when it makes a sufficient showing on all essential elements of its case to which it has the burden of proof. *Celotex Corp. v. Catrett*, 477 U.S. 317, 317–18 (1986). If the non-moving party fails to make a sufficient showing on an essential element of his case, on which he would bear the burden of proof at trial, summary judgment is proper. *Id*. at 322.

A nonmoving party may avert summary judgment by showing that there exist specific facts that would present a genuine issue for trial. *Id*. at 324. To establish a genuine issue of fact sufficient to warrant trial, the nonmoving party "must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). The nonmoving party must set forth "specific facts showing there is a genuine issue for trial." *Anderson*, 477 U.S. at 248 (quoting FED. R. CIV. P. 56(c)(2)).

IV. LEGAL ARGUMENT

Plaintiffs allege that the Box Hill Defendants were negligent in failing to provide patient-specific prescriptions in order to purchase medication from NECC. Assuming, *arguendo*, that such allegations are true for purposes of this motion, the undisputed facts in this matter are insufficient to establish either factual or proximate causation.

Under Maryland law, a plaintiff must allege sufficient facts to meet each element of a medical negligence claim, namely (1) the existence of a duty, (2) a breach of the duty, (3) that the plaintiff suffered actual injury or loss, and (4) that the loss or injury proximately resulted from the defendant's breach of the duty. *See Dehn v. Edgecombe*, 384 Md. 606, 619, 865 A.2d 603, 611 (2005); *Horridge v. Social Services*, 382 Md. 170, 182, 854 A.2d 1232, 1238 (2004); *Patton v. USA Rugby*, 381 Md. 627, 635-36, 851 A.2d 566, 570 (2004).

Causation is an essential element of a negligence claim. For a plaintiff to recover damages, a defendant's negligence must be a cause of the plaintiff's injuries. The causation element consists of factual and proximate cause. This Court is able to render a determination as to causation when the relevant facts of the underlying action, as they are in the instant matter, are not in dispute. *See Lashley v. Dawson*, 162 Md. 549, 563, 160 A. 738 (1932).

Factual cause is the "but for" aspect of causation. A negligent act is only deemed the factual cause of an outcome if, in the absence of the act, the outcome would have been avoided. *See Peterson v. Underwood*, 258 Md. 9, 16, 264 A.2d 851 (1970). Contrary to Plaintiffs' claims, the injuries sustained are the direct result of NECC's failure to properly manufacture and apply proper sterility and testing practices as to the MPA that they provided to the Box Hill Defendants.

Plaintiffs have failed to proffer any evidence to support a finding that the MPA produced by NECC would not have been contaminated if the Box Hill Defendants had ordered medications using patient-specific prescriptions. In fact, Plaintiffs' experts have testified in deposition that the allegedly negligent failure to order medication using patient-specific prescriptions had absolutely no impact on the fact that the medications produced by NECC were adulterated. Dr. Chason, Plaintiffs' expert pharmacist, adopted the findings detailed in his initial Report that "[i]t is clear that operational failures at New England Compounding Center were the *cause* of the [MPA] contamination involved in the 2012 fungal infection outbreak and that NECC's practices facilitated the appearance that it was closely regulated and operated as safely as a manufacturer." *See* Deposition Transcript of Dr. David Chason, 117:1–117:9, excerpts attached as **Exhibit 10**. Plainly stated, Dr. Chason agrees that NECC caused the contamination of the MPA. *See id.*, 118:11–118:14, excerpts attached as **Exhibit 10**. Dr. Saberski, Plaintiffs' pain medicine expert further testified that submitting patient-specific prescriptions had no effect on whether the drugs received

were contaminated and that ordering medication using patient-specific prescriptions would not have changed the outcome. *See* Deposition Transcript of Dr. Lloyd R. Saberski, 167:13–168:16, excerpts attached as **Exhibit 11**.

Accordingly, it is undisputed that NECC's failure to properly manufacture and apply proper sterility and testing practices as to MPA was the source of the contamination, not an alleged failure to provide patient-specific prescriptions. In other words, even assuming that the Box Hill Defendants had provided patient-specific prescriptions to the satisfaction of the Plaintiffs in this case, that would not have caused otherwise contaminated medication to transform into an unadulterated form to be administered to the Plaintiff patients. The Box Hill Defendants still would have received contaminated medication and the same outcome would have resulted. Therefore, the contamination occurred independent of the ordering practices of the Box Hill Defendants and the "but for" test necessarily fails as a matter of law. Absent a finding of causation in fact, no further analysis is necessary because the causation element is insufficient. *Mackin v. Harris*, 342 Md. 1, 8, 672 A.2d 1110 (1996).

Even assuming, *arguendo*, that the Plaintiffs have met their burden in establishing causation in fact, the Court must also find that the failure to provide patient-specific prescriptions was the proximate cause of Plaintiffs' injuries. Proximate cause involves a conclusion that someone will be held legally responsible for the consequences of an act or omission. *Peterson*, 258 Md. at 16. This determination is subject to considerations of fairness or social policy as well as mere causation. *Id*. Often, proximate causation is not proven because the negligent act was too far removed from the harm or the nature or extent of the harm was unforeseen. *See Peterson*, 258 Md. at 18–20. Further, the actor's conduct may be held not to be a legal cause of harm where after the event, looking back from the harm to the actor's negligent conduct, it appears to the court

highly extraordinary that it should have brought about the harm. *Hartford Ins. Co. v. Manor Inn*, 335 Md. 135, 157 n. 6, 642 A.2d 219. (1994). Ultimately, the proximate cause must be the natural and probable consequence of a negligent act. *Id*. at 159 (citing *Bloom v. Good Humor Ice Cream Company*, 179 Md. 384, 389 (1941)). As suggested, this is a determination made by the Court if the facts of the underlying action are not disputed, *Lashley v. Dawson*, 162 Md. 549, 563, 160 A. 738 (1932), as is the case here.

In order to support a finding of proximate cause, Plaintiffs' injuries "must be the natural and probable consequence" of the Box Hill Defendants' allegedly negligent act of ordering medication from NECC without using patient-specific prescriptions. There is no factual support or testimony in this matter that would support a conclusion. Rather, it is highly extraordinary that ordering medication from NECC without patient-specific prescriptions resulted in Plaintiffs' injuries. Stated differently, Plaintiffs are unable to demonstrate that the decision not to use patient-specific prescriptions would naturally and probably have resulted in NECC producing and distributing the contaminated MPA that caused Plaintiffs' injuries. It is undisputed that the Box Hill Defendants had been ordering MPA from NECC for years the same way with no adverse results. Plaintiffs' injuries were simply unforeseeable and too far removed from the Box Hill Defendant's alleged negligence in ordering medication from NECC without patient-specific prescriptions to support a finding of proximate cause.

Accordingly, the Box Hill Defendants are entitled to summary judgment as a matter of law because Plaintiffs are unable to establish either factual or proximate causation.

V. CONCLUSION

For the foregoing reasons, the Box Hill Defendants respectfully request that the Court grant its motion for summary judgment.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of September 2017, I served the above Memorandum upon the Clerk of the Court, using the CM/ECF system, which then sent a notification of such filing (NEF) to all counsel of record.

/s/ Gregory K. Kirby
Gregory K. Kirby, Esq.